COMPLEX COMMERCIAL LITIGATION

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April 7, 2011

VIA ECF AND FEDERAL EXPRESS

Honorable Nicholas G. Garaufis, U.S.D.J. U.S. District Court for the Eastern District of New York 225 Cadman Plaza Eastp Room 1416S Brooklyn, NY 11201

Re:

United States, et al. ex rel. Piacentile v. Novartis AG, et al.,

Case No.: 04-cv-4265

Dear Judge Garaufis:

We represent Relator Dr. Joseph Piacentile in the above-referenced matter. On March 22, 2011, defendant Novartis Pharmaceuticals Corporation ("NPC") filed a letter with this Court requesting a pre-motion conference in accordance with Your Honor's individual rules [Dkt. 91]. As an initial matter, Relator notes the curious timing of this request: certainly NPC could have raised a defense under Fed. R. Civ. P. 12(b)(1) in its initial moving papers. Instead, NPC waited for full adjudication of the motion taxing this Court's time and resources, chose to let the time to move for reconsideration lapse, and now advances to this Court (as will be demonstrated below) an utterly frivolous position that the Court could have dealt with had the issue been raised forthrightly by NPC.

Specifically, NPC seeks dismissal of Count III of the Amended Complaint which alleges that by way of NPC's pernicious kickback scheme to doctors in connection with the drug Visudyne, NPC did not report the best price of the drug to the Government causing the Government to overpay it, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(7).

NPC asserts that it plans to file a motion to dismiss this count based on the public disclosure bar of the False Claims Act. 31 U.S.C. § 3730(e)(4). NPC claims that the public disclosures include "numerous law suits [sic] brought by state and local governments against NPC alleging that NPC misreported its best price information by excluding free samples and other inducements from the best price calculation." [Dkt. 91 at p. 2]. NPC then cites two inapposite cases it relies on in support of dismissal, U.S. ex rel. Lisitza v. Johnson & Johnson No. 07-10288, 2011 U.S. Dist. LEXIS 19449 (D. Mass. Feb. 25, 2011) and U.S. ex rel. Schumann v. AstraZeneca PLC, No. 03-5423, 2010 U.S. Dist. LEXIS 109519 (D. Mass. Oct. 13, 2010).

NPC is essentially arguing that because there are myriad allegations regarding best price in an MDL in the District of Massachusetts, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456 (D. Mass), any allegations regarding best prices on drugs have already been publicly disclosed. But this argument is fatally flawed because with respect to *Novartis's illegal scheme regarding the drug Visudyne*, there has been no public disclosure. Indeed, the court in *Lisitza* rejected a best price allegation regarding the drugs Risperdal and Levaquin because in that very MDL there was a precise allegation regarding the drugs Risperdal and Levaquin. No. 1:03-cv-10643 (D. Mass.) Dkt. 4 ¶ 41 (part of MDL No. 1456). Novartis is a defendant in the MDL, and the complaint *only* alleges that Novartis committed best price fraud with respect to the drug Clozaril.

There has thus been no public disclosure of best price violations regarding the drug Visudyne. The public disclosure bar only precludes claims when a relator's claims are "substantially similar" to the publicly disclosed information. *U.S. ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 09-710, 2011 U.S. Dist. LEXIS 4862, at *18-19 (N.D.N.Y. Jan. 19, 2011) (citing *U.S. ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992)). The public disclosure must also comprise "the material elements of the allegations or transactions on which the claim is based." *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 103 (2d Cir.), *cert. granted*, 131 S. Ct. 63 (2010).

Here, the public disclosure is devoid of *all* of the material elements of the transaction. Specifically, the conduct as alleged by the Relator is eminently different than the conduct identified in the public disclosures *and* arguably the single most material element of the allegation – *the drug itself* – is different. NPC cannot point to any public disclosure before the instant lawsuit was filed that identified even remotely the same pernicious conduct as alleged in the Amended Complaint with respect to Visudyne. Under NPC's bizarre theory of the public disclosure bar, a relator or other entity could bring a best price lawsuit against a company alleging entirely different conduct relating to an entirely different drug and that lawsuit would serve as a virtual litigation bar to any other lawsuit relating to *different conduct* concerning *different drugs*. This is simply not what Congress intended; given that the public disclosure bar has been interpreted nearly universally by courts to require "substantial similar[ity]" between a claim and a previously disclosed allegation, NPC's argument necessarily fails.

The fraudulent scheme Relator has alleged in this case is very specific – amorphous disclosures regarding completely different drugs do not trigger the public disclosure bar because they are simply not "adequate to set the government squarely on the trail of fraud." *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 538 F. Supp. 2d 367, 387 (D. Mass. 2008) (where relator alleged specific fraudulent scheme that defendants argued was part and parcel of broader scheme, public disclosure bar not triggered) (quoting *U.S. ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 571-72 (10th Cir. 1995)).

Relator does not oppose the request for a pre-motion conference; he only seeks to correct a misleading record sown by NPC. The public disclosure bar simply has no applicability to the instant case.

We thank the Court for its kind attention to this matter.

Respe	ectfully submitted	d,
/s/Da	vid S. Stone	

cc: All Counsel (via ECF only)